REMARKS

Applicants wish to thank the examiner for the courtesy extended to their undersigned representative during the March 25, 2004 interview. Claims 12 and 26-28 are pending. Claim 12 is amended herewith to add reference to a carrier. Support for this amendment appears throughout the specification and claims as filed. No new matter is introduced by this amendment.

Rejection under 35 U.S.C. 102(b)

Claim 12 is rejected as anticipated by Schutt (US 4,248,861), Rosenbaum (US 5,585,386) and Kubo (JP 11-189541). For reasons stated in Applicants' response submitted December 19, 2002 and discussed in the aforementioned interview, Applicants submit that Schutt, Rosenbaum and Kubo do not anticipate claim 12. Applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. 103(a)

Claim 12 is rejected as obvious in view of Schutt (US 4,248,861), Rosenbaum (US 5,585,386) and Kubo (JP 11-189541). For reasons stated in Applicants' response submitted December 19, 2002 and discussed in the aforementioned interview, Applicants submit that Schutt, Rosenbaum and Kubo do not render claim 12 obvious.

Applicants have identified a combination of three specific kavalactones (i.e., kawain, dihydrokawain, and dihydromethysticin) that exhibit superior IL-12 inhibitory activity (see, FIG. 1). The activity of this specific combination (out of the more than 16 different kavalactones known) was not previously recognized or appreciated. Moreover, the claimed composition having the stated percentage (relative to the total ointment composition) of the three IL-12 active kavalactones was not previously envisioned. Neither Schutt, Rosenbaum nor Kubo, either alone or in combination, provide any motivation to select out the combination of these three kavalactones, nor provide any motivation for a composition having the stated percentages of the combination (relative

to the total ointment composition). In light of the lack of identification of a motivation in Schutt, Rosenbaum or Kubo to arrive at Applicants' claimed composition, Applicants request withdrawal of this rejection.

Claims 26-28 are rejected as obvious in view of Asmussen (US 6,379,696), Elbakyan (WO 00/30578) and Schwabe (US 5,296,224). For reasons stated in Applicants' response submitted December 19, 2002 and discussed in the aforementioned interview, Applicants submit that Asmussen, Elbakyan and Schwabe do not render claims 26-28 obvious.

Again, Applicants have identified a combination of three specific kavalactones (i.e., kawain, dihydrokawain, and dihydromethysticin) that exhibit superior IL-12 inhibitory activity (see, FIG. 1). The activity of this specific combination (out of the more than 16 different kavalactones known) was not previously recognized or appreciated. Moreover, the claimed composition having the stated percentage (relative to the total ointment composition) of the three IL-12 active kavalactones was not previously envisioned. Neither Asmussen, Elbakyan nor Schwabe, either alone or in combination, provide any motivation to select out the combination of these three kavalactones, nor provide any motivation for a composition having the stated percentages of the combination (relative to the total ointment composition). In light of the lack of identification of a motivation in Asmussen, Elbakyan, or Schwabe to arrive at Applicants' claimed composition, Applicants request withdrawal of this rejection.

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In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. Should the application not be considered in condition for allowance, Applicants request the examiner to telephone their undersigned representative to discuss the application. Applicants thank the examiner in advance for this courtesy.

Dated: May 7, 2004   Respectfully submitted,

By _____
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